New Horizons 2021

New Agents for GIST Patients

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GIST Overview

- Most common GI sarcoma
  - 0.2% of all GI tumors, but 80% of GI sarcomas
- High frequency of metastatic disease
- Gene mutations drive phenotype and therapy
- Metastatic disease treated with tyrosine kinase inhibitors (TKIs)
  - **Imatinib** (PFS = 24 months)
  - **Sunitinib** (PFS = 6 months)
  - **Regorafenib** (PFS = 5 months)

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  - **Ripretinib** (PFS = 6.3 months)
  - **Avapritinib (PFS = 3.7 months)**

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  - **Ripretinib** (PFS = 6.3 months)
  - **Avapritinib (PFS = 3.7 months)**
  - **Avapritinib PDGFR (PFS = NR)**

GIST Subtypes

Kit exon 11

Kit exon 9

KIT resistance mutations

Exon 13 (ATP binding site)

Exon 17 (A-loop)

PDGFR D842V

SDH deficiency

Raf V600E

NF-1, Ras

PI3K

IGF-1R expressing

TRK fusion

Personal Communication Jon Trent, MD, PhD (Sylvester Comprehensive Cancer Center)

GIST Subtypes and Treatment

- Kit exon 11: Imatinib 400 mg
- Kit exon 9: Imatinib 800mg (or tolerated dose)
- PDGFR D842V: avapritinib
- SDH deficiency: Sunitinib or Regorafenib (TMZ trial)
- Raf V600E: Raf inhibitor
- NF-1, Ras: Raf or Mek inhibitor
- PI3K: mTOR inhibitor
- IGF-1R expressing – IGF-1R inhibitor trial
- TRK fusion – Larotrectenib NTRK inhibitor
- KIT resistance mutations
  - Exon 13 (ATP binding site): Sunitinib 37.5 mg daily
  - Exon 17 (A-loop): Regorafenib or Ripretinib

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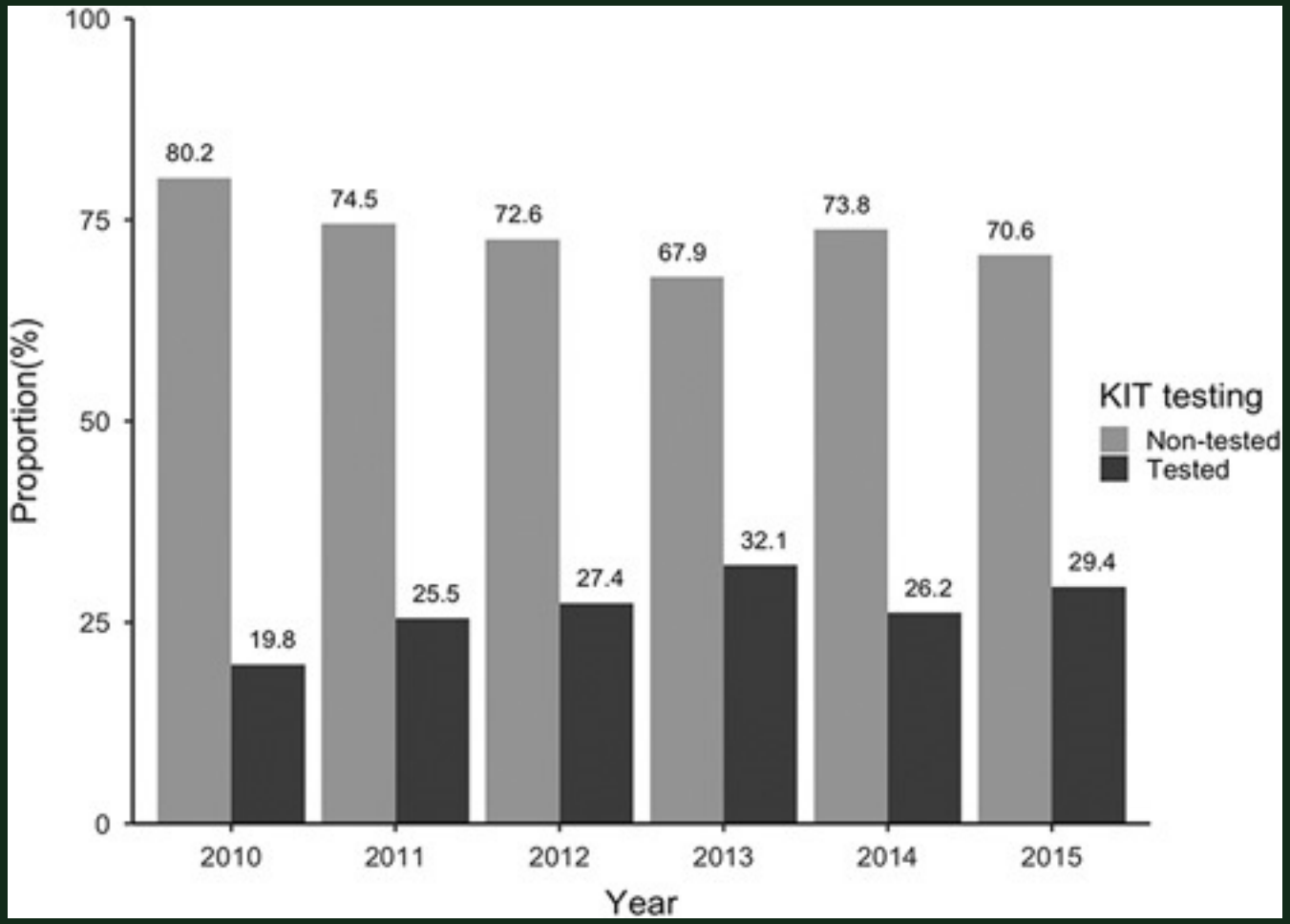
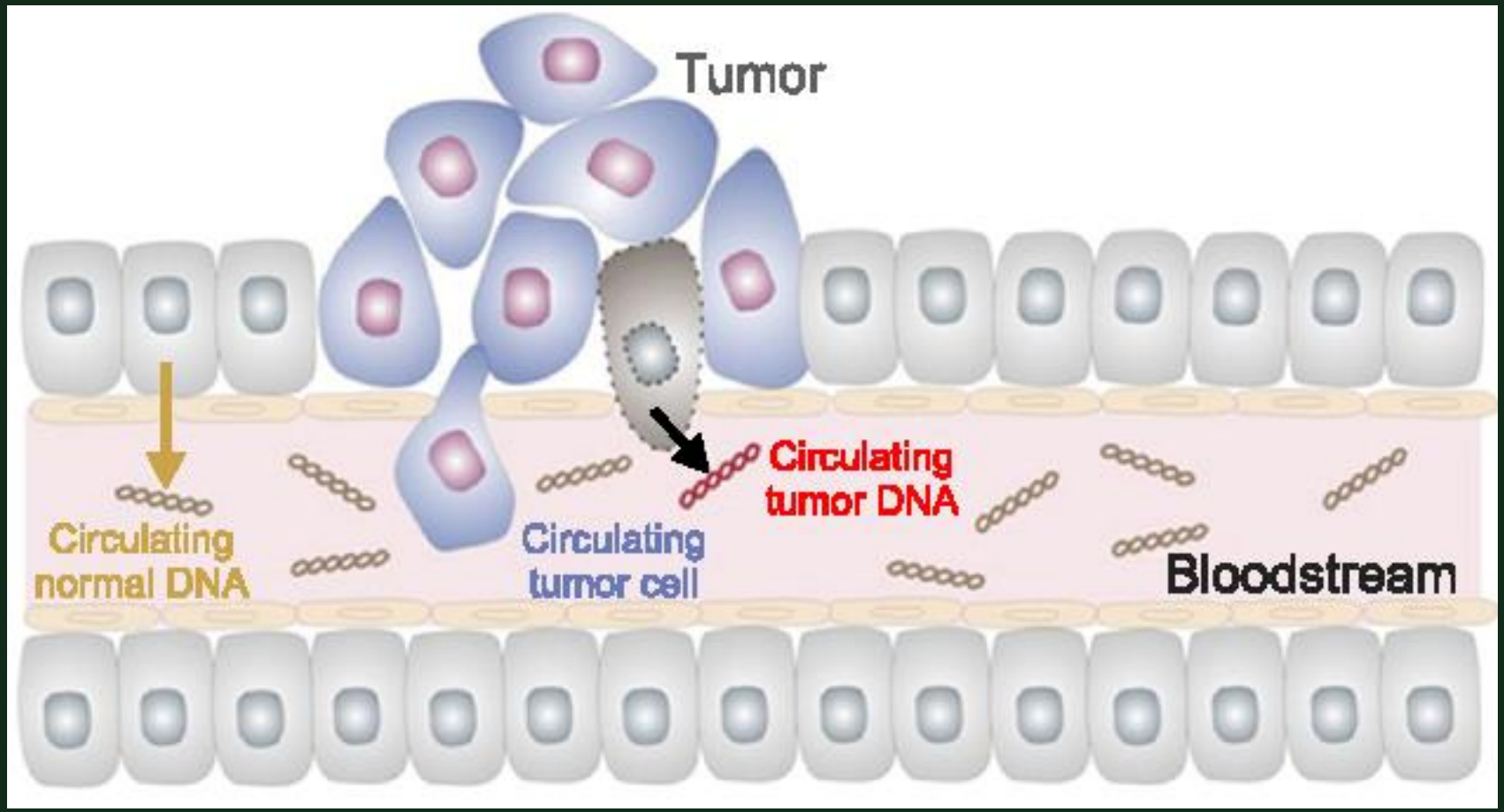
GIST mutation testing in US



Florindez and Trent American Journal of Clinical Oncology43(4):270-278, April 2020.

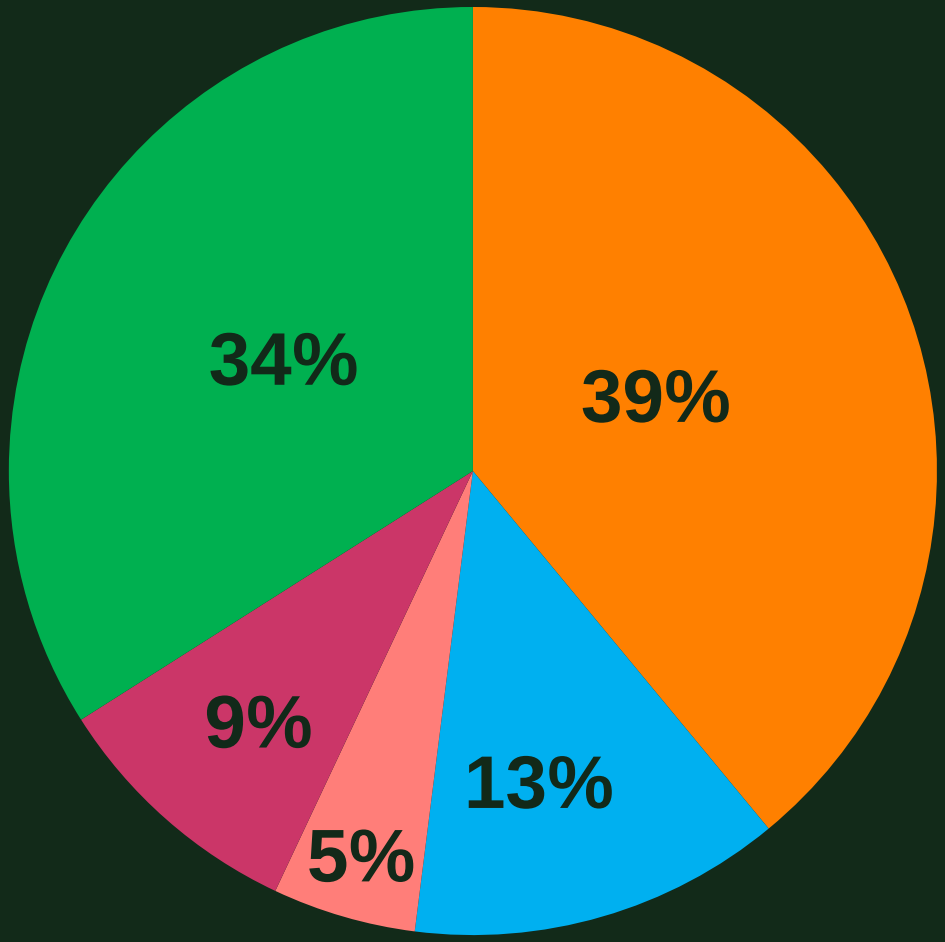
Circulating Tumor DNA

Mutation Testing From Blood (Liquid Biopsy)



Nurwidya et al, 2018
Bauer JCO 2015
Serrano BJC 2018

Distribution of Primary Mutations (%)

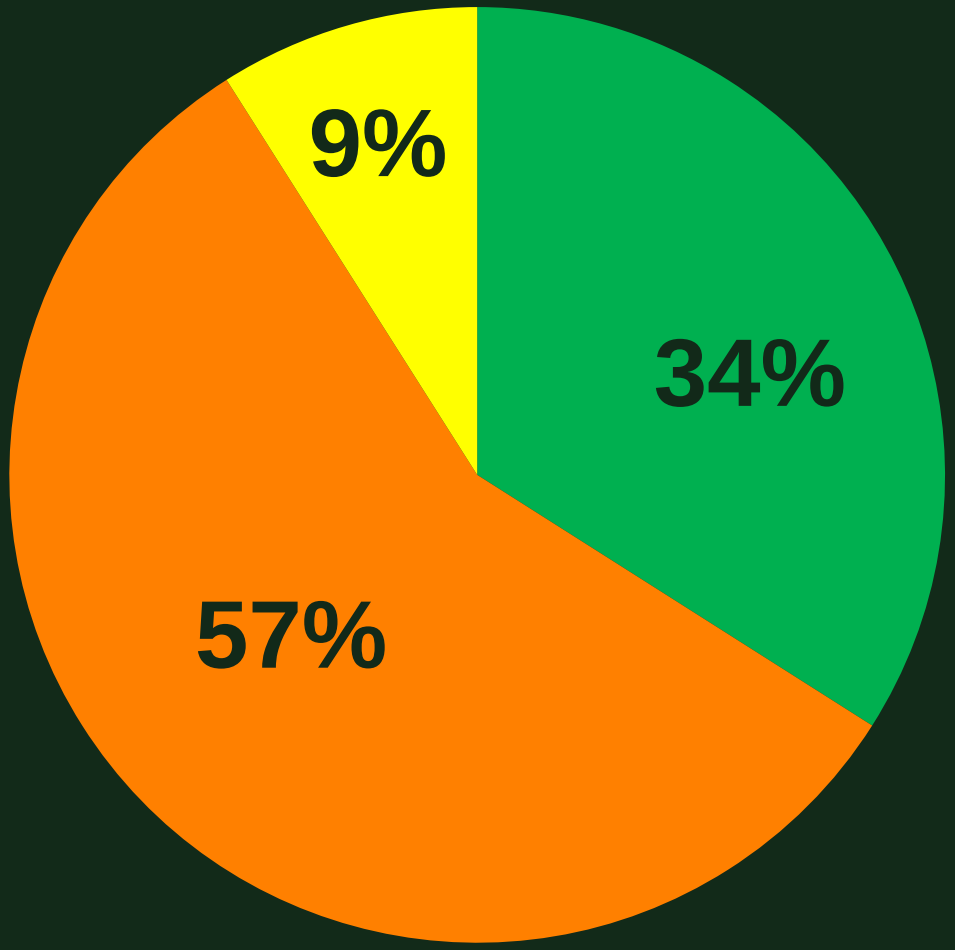


- Patients with mutation (n=162)
- KIT or PDGFR mutations (N=106)
- Not KIT/PDGFR (N=56)

Kit exon 11 KIT exon 9 KIT other
PDGFR Other

Junaid Arshad, Jonathan C. Trent. JCO Precision Oncology 2020 :4, 66-73

Resistance Mutations (%)



- Patients with KIT or PDGFR mutation (n=106)
- Other: Ras, NF-1, PI3K, TSC

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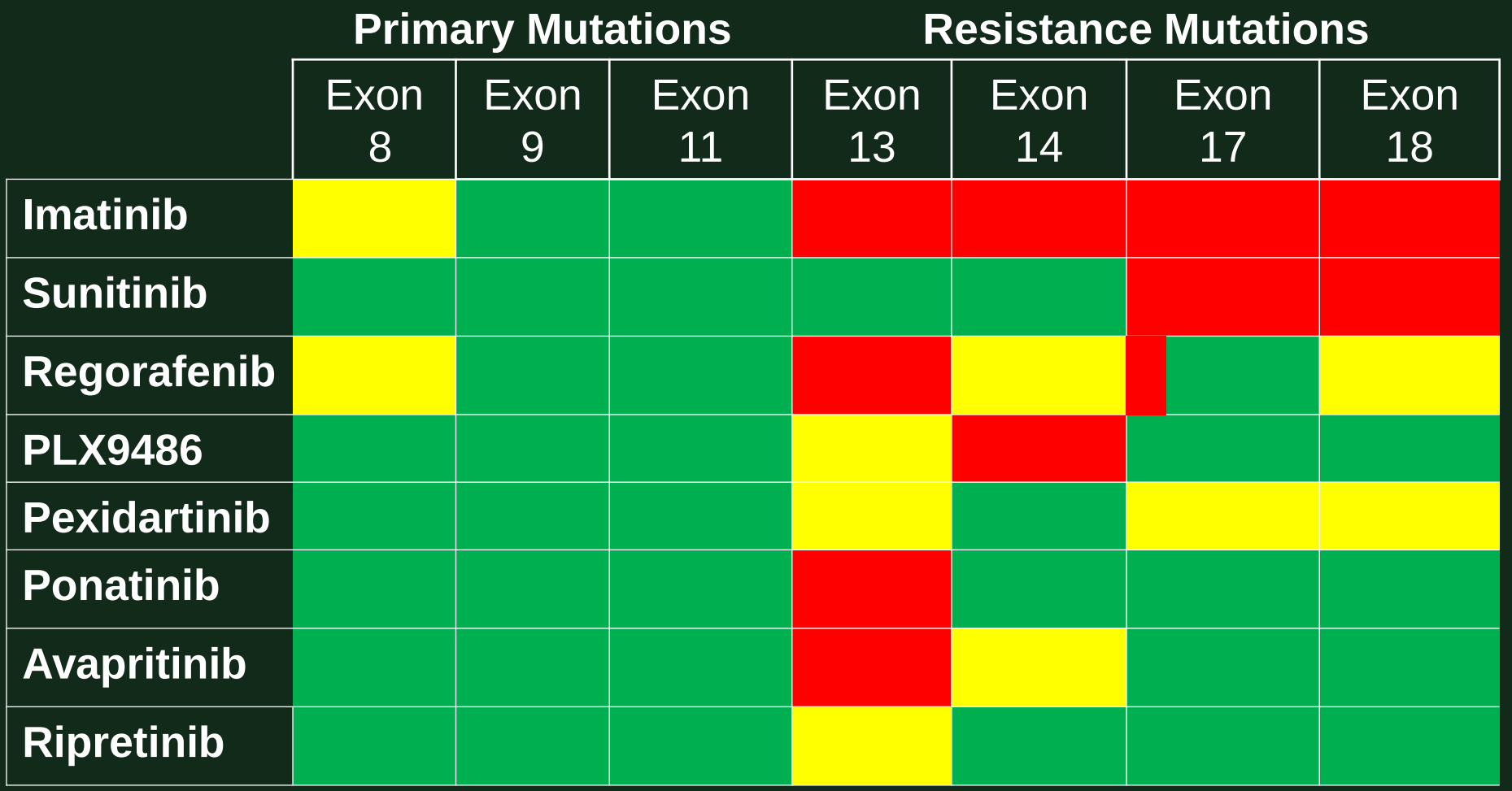
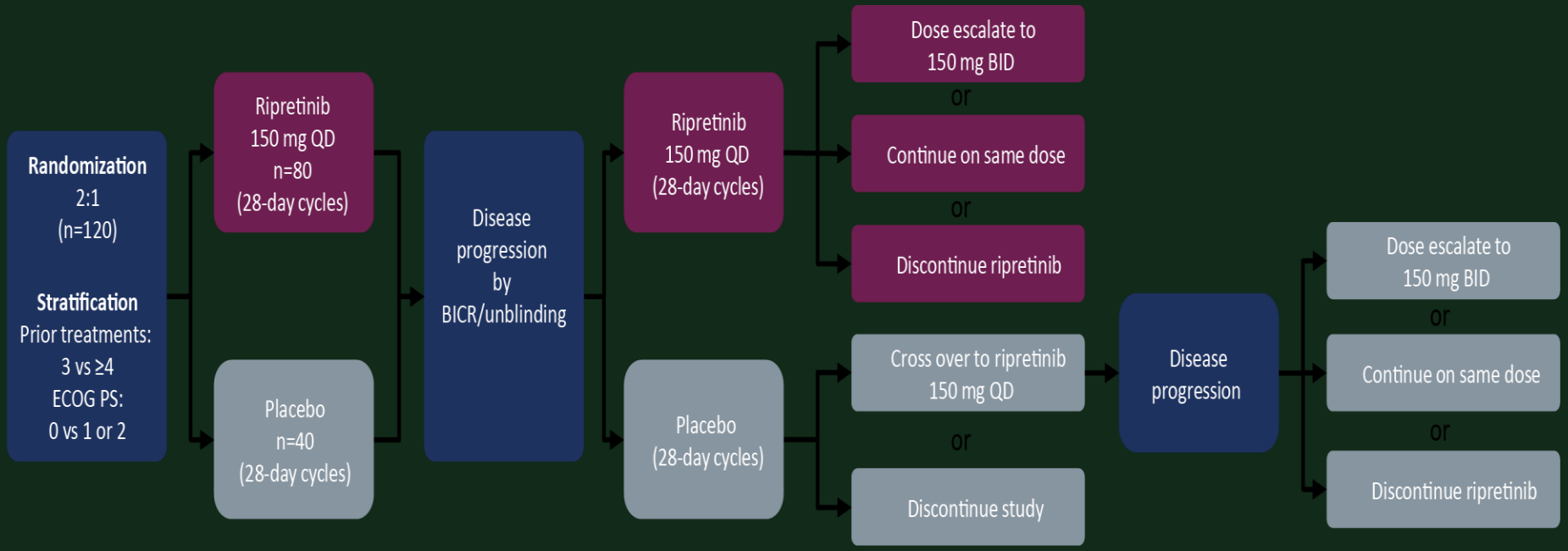
Differential Sensitivity to TKI



Junaid Arshad, Jonathan C. Trent. JCO Precision Oncology 2020 :4, 66-73

Trent, CTOS 2017; Serrano BJC 2018
Gramza et al, Clinical Cancer Research 15:7510, 2009
Heinrich et al, ASCO 2013 Poster/Abstract 10509

Ripretinib INVICTUS Study Design



Blay JB, et al. *Lancet Oncology*. Published online June 5, 2020

BICR, blinded independent central review; BID, twice daily; QD once daily.

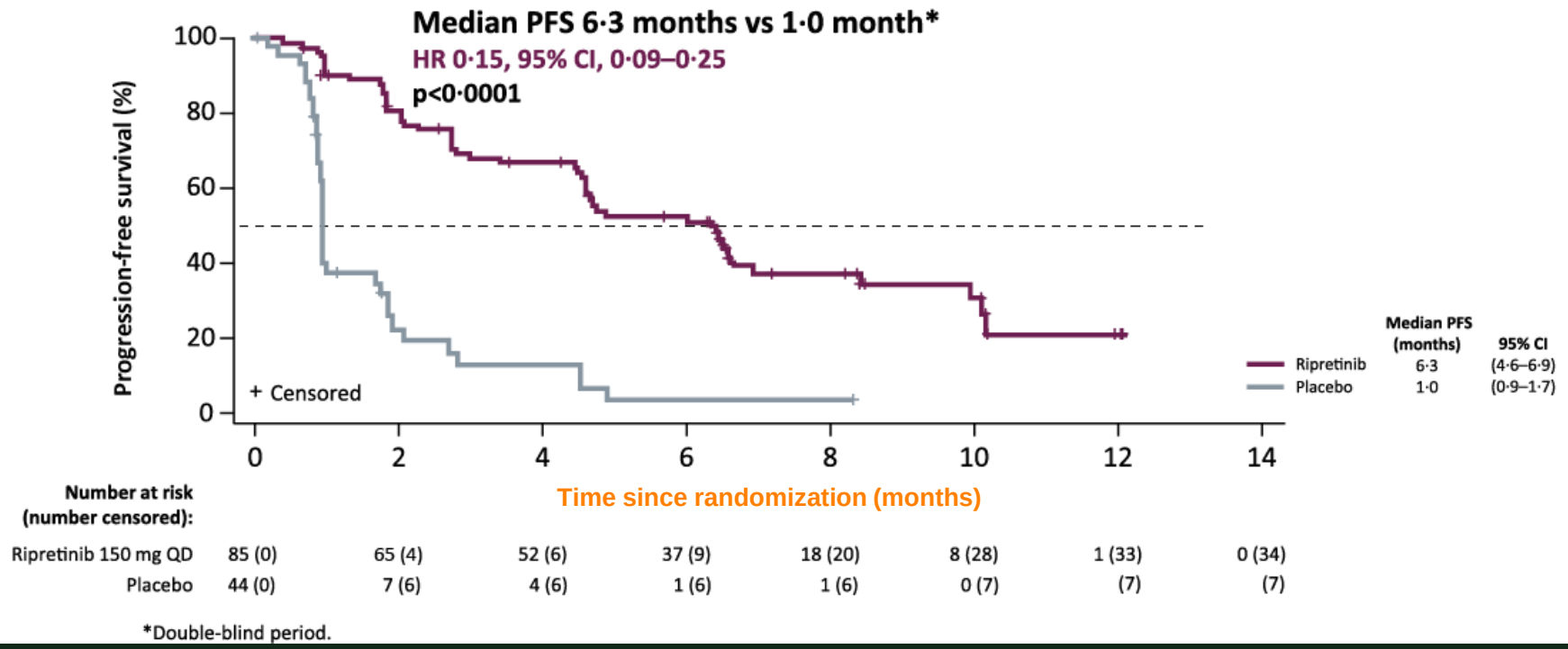
Data cutoff
May 31, 2019

Baseline patient characteristics

Characteristic	Ripretinib (n=85)	Placebo (n=44)
	number of patients (percent)	
Age, median (min, max), y	59 (29, 82)	65 (33, 83)
18–64	57 (67%)	22 (50%)
65–74	20 (24%)	12 (27%)
≥75	8 (9%)	10 (23%)
Sex		
Male	47 (55%)	26 (59%)
Race		
White	64 (75%)	33 (75%)
Region		
United States	40 (47%)	20 (46%)
Number of prior therapies		
3	54 (64%)	27 (61%)
≥4 (range, 4–7)	31 (36%)	17 (39%)
ECOG PS		
0	37 (44%)	17 (39%)
1 or 2	48 (56%)	27 (61%)

Characteristics	Ripretinib (n=85)	Placebo (n=44)
Primary tumor site		
Gastric	40 (47.1%)	18 (40.9%)
Jejunum/ileum	20 (23.5%)	8 (18.2%)
Mesenteric/omental	6 (7.1%)	6 (13.6%)
Other	7 (8.2%)	4 (9.1%)
Duodenum	2 (2.4%)	8 (18.2%)
Colon/rectum	9 (10.6%)	0
Unknown	1 (1.2%)	0
Sum of longest diameters of target lesions (mm), median (range)*	123.1 (28–495)	141.7 (17–412)
Primary mutation (central testing of tumor tissue)		
KIT exon 9	14 (17%)	6 (14%)
KIT exon 11	47 (55%)	28 (64%)
Other KIT	2 (2%)	2 (5%)
PDGFRA	3 (4%)	0

Ripretinib significantly improved mPFS vs. placebo



mPFS of 6·3 months vs 1.0 month
(HR 0·15, 95% CI 0·09–0·25; p<0·0001)

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Objective Response Rate

	Ripretinib (n=85) n (%; 95% CI)	Placebo (n=44) n (%; 95% CI)	p value
Confirmed objective response	**8 (9%; 4–18)**	**0 (0–8)**	**0.0504**
Complete response	0 (0%; 0–4)	0 (0%; 0–8)	
Partial response	8 (9%; 4–18)	0 (0%; 0–8)	
Stable disease 6 wk	56 (66%; 55–76)	9 (20%; 10-35)	
Stable disease 12 wk	40 (47%; 36–58)	2 (5%; 1–16)	
Progressive disease	16 (19%; 11–29)	28 (64%; 48–78)	
Not evaluable	4 (5%)	3 (7%)	
No response assessment	1 (1%)	4 (9%)	

- Median time to best response 1.9 months (IQR, 1.0–2.7)
- Median time to progression
  - Ripretinib 6.4 months (95% CI, 4.6–8.4)
  - Placebo 1.0 months (95% CI, 0.9–1.7)

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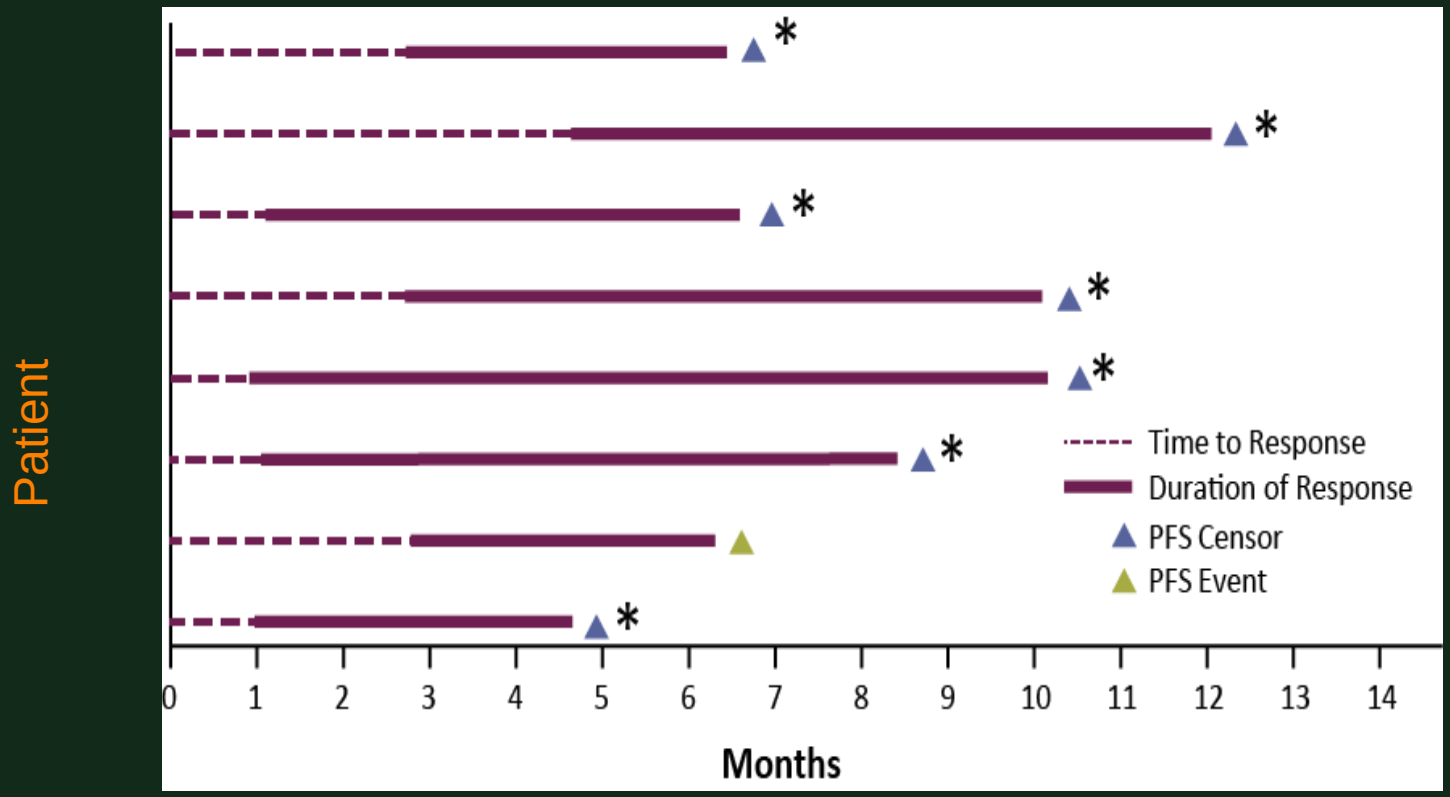
Time to Response and Duration of Response



- Median duration of response not yet reached as of data cutoff
- 1 of the 8 responding patients had disease progression as of data cutoff

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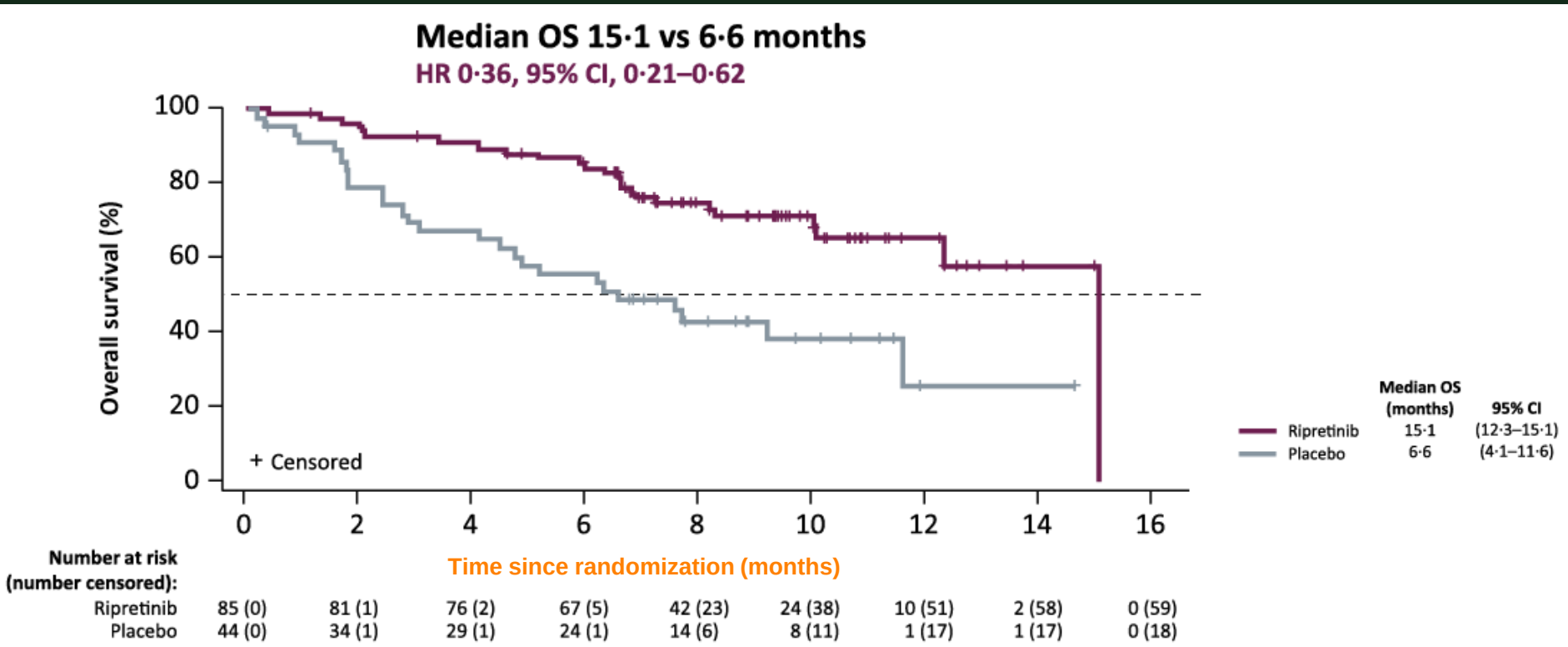
Overall Survival*



Events were reported in 26 (30·6%) of 85 patients receiving ripretinib and 26 (59·1%) of 44 patients receiving placebo.

Blay/pg7/col1/p 4

Includes double-blind and open-label periods.
*Owing to hierarchal testing procedures of the endpoints, overall survival could not be formally tested for statistical significance because the objective response was not significant (ORR for ripretinib did not meet our predefined assumption of 22%)

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Treatment-Related TEAEs

	Ripretinib (n=85)				Placebo (n=44)*			
Preferred Term	Grade 1–2	Grade 3	Grade 4	Grade 5	Grade 1–2	Grade 3	Grade 4	Grade 5
Alopecia	42 (49%)†	..	..	..	1 (2%)	..	..	..
Myalgia	23 (27%)	1 (1%)	..	..	4 (9%)	0	..	..
Nausea	21 (25%)	1 (1%)	..	..	1 (2%)	0	..	..
Fatigue	20 (24%)	2 (2%)	..	..	6 (14%)	1 (2%)	..	..
PPES	18 (21%)‡	0	..	..	0	0	..	..
Diarrhea	17 (20%)	1 (1%)	0	0	2 (5%)	1 (2%)	0	0
Constipation	13 (15%)	0	0	0	3 (7%)	0	0	0
Decreased appetite	12 (14%)	1 (1%)	0	0	2 (5%)	1 (2%)	0	0
Weight decreased	13 (15%)	0	..	..	3 (7%)	0	..	..
Blood bilirubin increased	12 (14%)	0	0	..	0	0	0	..
Arthralgia	10 (12%)	0	..	..	0	0	..	..
Muscle spasms	10 (12%)	0	..	..	2 (5%)	0	..	..
Hypertension	4 (5%)	3 (4%)	0	0	1 (2%)	0	0	0
Lipase increased	4 (5%)	4 (5%)	0	..	0	0	0	..
Pain in extremity	5 (6%)	1 (1%)	..	..	1 (2%)	0	..	..
Hypophosphatemia	3 (4%)	2 (2%)	0	0	0	0	0	0

Data are in n(%). Treatment-related TEAEs are listed that occurred in ≥ 10% of patients in either treatment group or were reported as grade 3, 4, or 5 in either treatment group.
*All patients were randomly assigned to receive placebo, but one patient did not receive treatment.
†24 (65%) of 38 women who were given ripretinib had alopecia.
‡All PPES events were grade 1 (11 [13%]) or grade 2 (7 [9%]).
GERD, gastroesophageal reflux disease; GI, gastrointestinal; PPES, palmar plantar erythrodysesthesia syndrome.

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Treatment-Related TEAEs

	Ripretinib (n=85)				Placebo (n=44)*			
Preferred Term	Grade 1–2	Grade 3	Grade 4	Grade 5	Grade 1–2	Grade 3	Grade 4	Grade 5
Blood triglycerides increased	1 (1%)	1 (1%)	0	0	0	0	0	0
Dermatosis	1 (1%)	1 (1%)	0	0	0	0	0	0
Dehydration	1 (1%)	0	0	0	0	1 (2%)	0	0
GERD	1 (1%)	1 (1%)	..	..	0	0	..	..
Hyperkalemia	0	1 (1%)	0	0	0	1 (2%)	0	0
Hypokalemia	0	1 (1%)	0	0	0	0	0	0
Anal abscess	0	1 (1%)	0	0	0	0	0	0
Ascites	0	1 (1%)	0	0	0	0	0	0
Cardiac failure	0	1 (1%)	0	0	0	0	0	0
Death, reason unknown	..	..	..	1 (1%)	..	..	..	0
Fecaloma	0	1 (1%)	0	0	0	0	0	0
Skin infection	0	1 (1%)	0	0	0	0	0	0
Syncope	..	1 (1%)	..	..	..	0	..	..
Upper GI hemorrhage	0	1 (1%)	0	0	0	0	0	0
Acute kidney injury	0	0	0	0	0	1 (2%)	0	0

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Conclusions

- **Ripretinib as 4th line+ therapy** for advanced GIST patients significantly improved outcomes compared to placebo
  - mPFS: **ripretinib = 6.3 months** vs placebo = 1.0 months
    - (HR 0.15, 95% CI, 0.09–0.25)
  - ORR: **ripretinib = 9%** vs placebo = 0%
    - (*P*=0.0504)
  - mOS: **ripretinib = 15.1 months** vs placebo = 6.6 months
    - (HR 0.36, 95% CI, 0.21–0.62)
- **29 (66%) of 44 patients in the placebo group crossed over** to ripretinib possibly underestimating OS.
- **Durable responses** with ripretinib were observed (NR)

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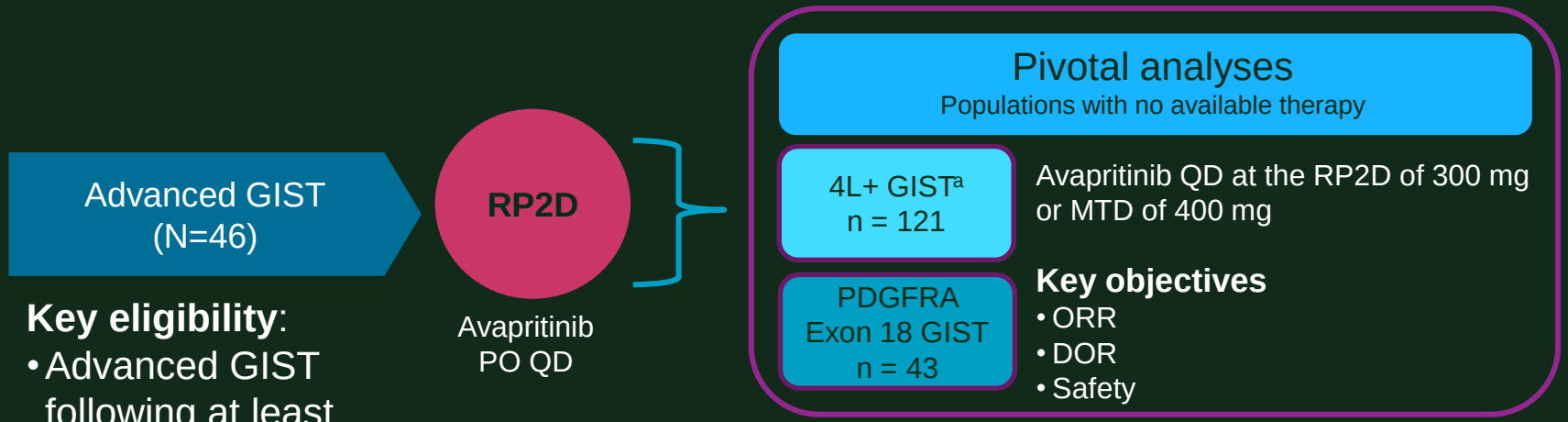
STUDY DESIGN AND OBJECTIVES

NAVIGATOR is an open-label, dose escalation/dose expansion phase 1 study of avapritinib



Key eligibility:
- Advanced GIST following at least 2 prior lines of TKI therapy
- Mutation in KIT or PDGFRA

Data are based on a data cut-off date of November 16, 2018.
Avapritinib is an investigational agent discovered and currently in development by Blueprint Medicines Corporation

Patient Baseline Demographics and Disease Characteristics

Characteristic	PDGFRA Exon 18 (n=43)	4L+ (n=121)
Age, median (min–max)	64 (29–90)	59 (33–80)
Sex, % (n)		
Male	67.4 (29)	57.9 (70)
Race, % (n)		
White	67.4 (29)	71.1 (86)
GIST mutational subtype, % (n)		
KIT	0	90.9 (110)
PDGFRA D842V	88.4 (38)	6.6 (8)
PDGFRA Exon 18 non-D842V[a]	11.6 (5)	2.5 (3)
Number of prior lines of TKIs, median (range)	1 (0–5)	4 (3–11)
Metastatic disease, % (n)	97.7 (42)	98.3 (119)
Largest target lesion (central radiology review), % (n)		
≤5 cm	46.5 (20)	33.1 (40)
>5 to ≤10 cm	32.6 (14)	47.1 (57)
>10 cm	20.9 (9)	18.2 (22)
Prior surgical resection, % (n)		
Yes	86.0 (37)	88.4 (107)
ECOG PS, % (n)		
0	32.6 (14)	32.2 (39)
1	60.5 (26)	64.5 (78)
2	7.0 (3)	3.3 (4)

[a]PDGFRA Exon 18 non-D842V mutations including D842Y, DI 842-845V, I843_D846del, I843_D846del, and D842-H845. ECOG PS, Eastern Cooperative Oncology Group performance status; GIST, gastrointestinal stromal tumor; TKI, tyrosine kinase inhibitor.

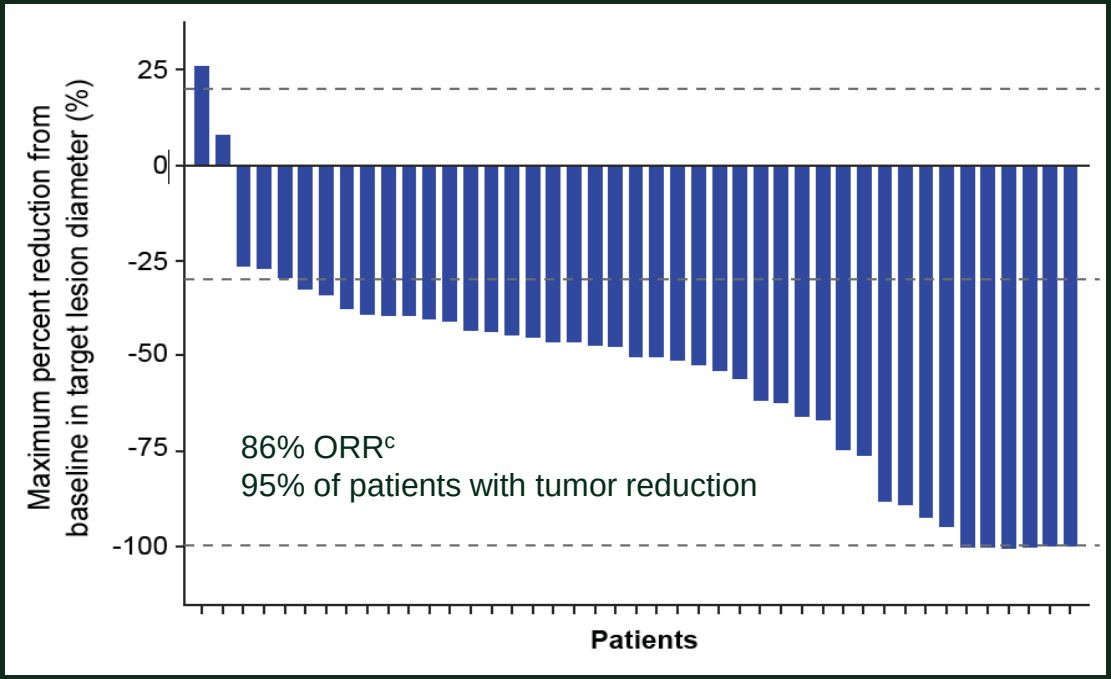
RESULTS

Most Common AEs Occurring in ≥ 15% of Patients, % (n)	300/400 mg QD Starting Dose (N = 204)			
	All AEs		Treatment-related AEs	
	All Grades[b]	Grade ≥3[c]	All Grades[b]	Grade ≥3[c]
Nausea	64.2 (131)	2.5 (5)	59.3 (121)	-
Fatigue	55.4 (113)	7.4 (15)	47.1 (96)	6.4 (13)
Anemia	50.0 (102)	28.4 (58)	36.3 (74)	16.2 (33)
Cognitive effects[a]	41.2 (84)	3.9 (8)	41.2 (84)	3.9 (8)
Periorbital edema	40.7 (83)	-	40.2 (82)	-
Vomiting	38.2 (78)	2.0 (4)	31.9 (65)	-
Decreased appetite	37.7 (77)	2.9 (6)	28.4 (58)	-
Diarrhea	37.3 (76)	4.9 (10)	31.9 (65)	2.9 (6)
Increased lacrimation	32.8 (67)	-	30.4 (62)	-
Peripheral edema	30.9 (63)	-	27.0 (55)	-
Face edema	24.5 (50)	-	24.0 (49)	-
Constipation	22.5 (46)	-	-	-
Dizziness	22.1 (45)	-	-	-
Hair color changes	21.1 (43)	-	20.6 (42)	-
Blood bilirubin increased	21.1 (43)	4.4 (9)	18.6 (38)	3.9 (8)
Abdominal pain	20.1 (41)	5.4 (11)	-	-
Headache	16.7 (34)	-	-	-
Dyspnea	16.7 (34)	2.5 (5)	-	-
Dyspepsia	15.7 (32)	-	-	-
Hypokalemia	15.7 (32)	2.9 (6)	-	-
Dysgeusia	15.2 (31)	-	15.2 (31)	-

- Most AEs were grade 1 or 2
  - 400 mg > 300 mg QD dose group
- No grade 5 TRAEs
- Most remained on treatment
  - dose intensity was 86% at 300 mg QD and 73% at 400 mg QD
- 8.3% of patients discontinued avapritinib for TRAE in the 300/400 mg QD group
  - 2.0% discontinued treatment for cognitive effects

[a]Cognitive effects include pooled terms of memory impairment (29.4%), cognitive disorder (10.8%), confusional state (7.4%), and encephalopathy (1.5%). Blueprint Medicines considered all cognitive effect AEs as treatment-related in this analysis. Note: 3 events of intracranial hemorrhage occurred; 2 were grade 3, 1 was grade 1. [b]All grades AEs occurring in ≥15% of patients. [c]Grade ≥3 AEs occurring in ≥2% of patients. AE, adverse event; QD, once daily.

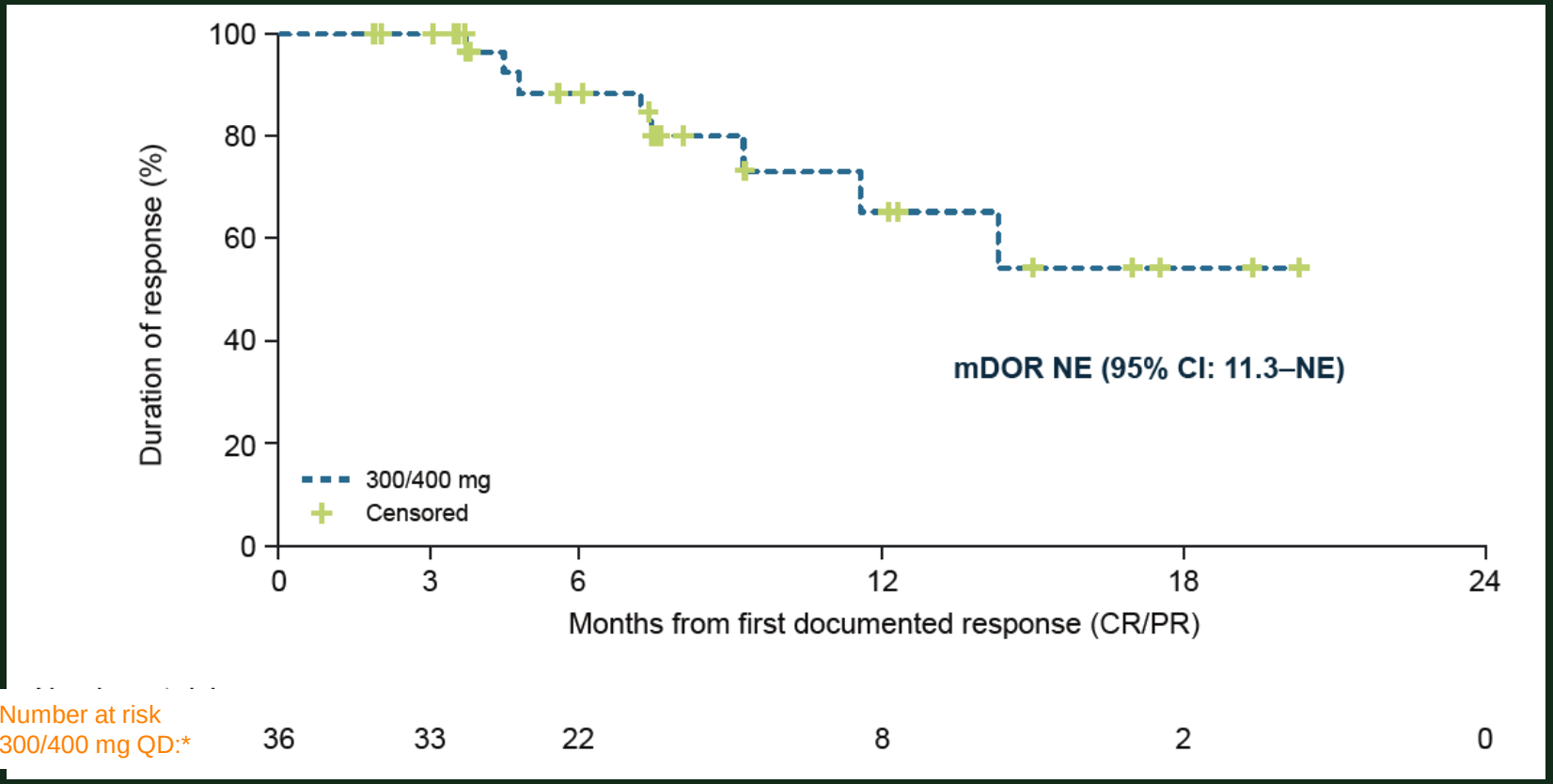
Antitumor Activity (Central Radiology Review): PDGFRA Exon 18 Avapritinib 300/400 mg QD Starting Dose



Best Response,[a] n	PDGFRA Exon 18 n=43
CR	3
PR[b]	34 (1 pending)
SD	5
PD	1
ORR (CR+PR), [c] % (95% CI)	86.0 (72.1–94.7)
CBR,[d] % (95% CI)	95.3 (84.2–99.4)
DOR,[e] months (95% CI)	NE (11.5–NE)
PFS, months (95% CI)	NE (13.4–NE)

[a]Assessed by mRECIST 1.1. Patients who have had ≥1 post-baseline radiographic assessment. Response-evaluable at 300/400 mg QD. [b]1 response pending confirmation. [c]ORR defined as the proportion of patients with a confirmed best response of CR or PR. [d]CBR defined as CR/PR+SD lasting ≥16 weeks from first dose. [e]DOR defined as the time from first documented response (CR/PR) to the date of first documented disease progression or death due to any cause, whichever came first. CBR, clinical benefit rate; CI, confidence interval; CR, complete response; DOR, duration of response; mRECIST, modified Response Evaluation Criteria in Solid Tumors; NE, not evaluable; ORR, overall response rate; PD, progressive disease; PDGFRA, platelet-derived growth factor receptor alpha; PFS, progression-free survival; PR, partial response; QD, once daily; SD, stable disease.

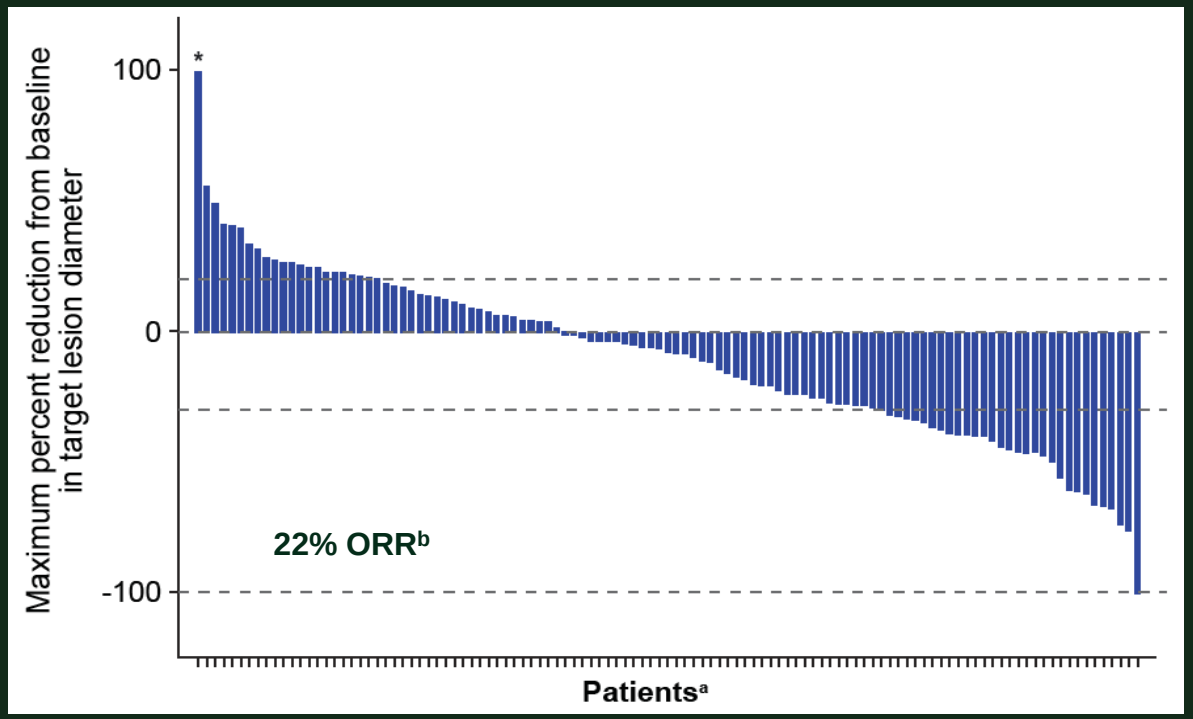
Duration of Response
PDGFRA Exon 18 Avapritinib 300/400 mg QD



- 78% (28/36) of PDGFRA Exon 18 patients were still in response as of the November 16, 2018, data cutoff
- Median follow-up was 10.9 months

*Patients with confirmed response. DOR was defined as the time from first documented response (CR/PR) to the date of the first documented disease progression or death due to any cause, whichever came first. Patients without confirmed CR/PR were excluded from this analysis. CI, confidence interval; CR, complete response; mDOR, median duration of response; NE, not evaluable; NR, not reached; PDGFRA, platelet-derived growth factor receptor alpha; PR, partial response; QD, once daily.

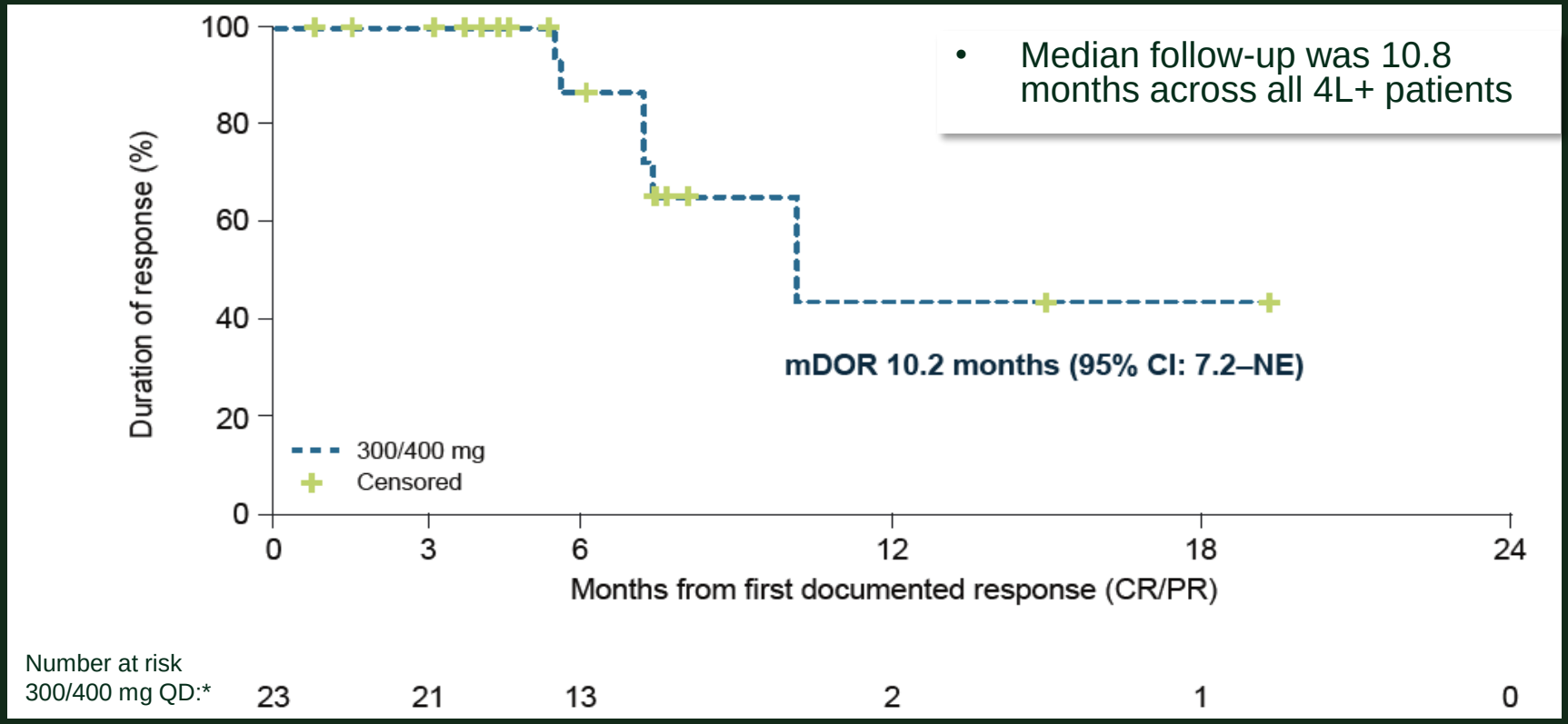
Antitumor Activity (Central Radiology Review) 4L+ Avapritinib 300/400 mg QD Starting Dose



Best Response[c], n	4L+ N=111
CR	1
PR (confirmed)	23 (1 pending)
SD	52
PD	35
ORR (CR+PR), % (95% CI)	22 (14.4–30.4)
CBR, % (95% CI)	41 (32.2–51.2)
DOR, months (95% CI)	10.2 (7.2–NE)
PFS, months (95% CI)	3.7 (3.4–5.6)

*One patient had an outlier value for percent change from baseline of >200% increase in target lesion diameter. [a]Two patients who had best response assessment are not included in the waterfall plot because they did not have measurable target lesions at baseline and thus, no percent change could be calculated. [b]There were 8 patients with PDGFRA D842V mutations and when these patients were removed from analysis, the ORR was 17% and DOR remained unchanged. [c]Assessed by mRECIST 1.1. Patients who have had ≥1 post-baseline radiographic assessment. Response-evaluable at 300/400 mg QD. CBR, clinical benefit rate; CI, confidence interval; CR, complete response; DOR, duration of response; mRECIST, modified Response Evaluation Criteria in Solid Tumors; NE, not evaluable; ORR, overall response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; QD, once daily; SD, stable disease.

Duration of Response
4L+ Avapritinib 300/400 mg QD Starting Dose



- Median follow-up was 10.8 months across all 4L+ patients

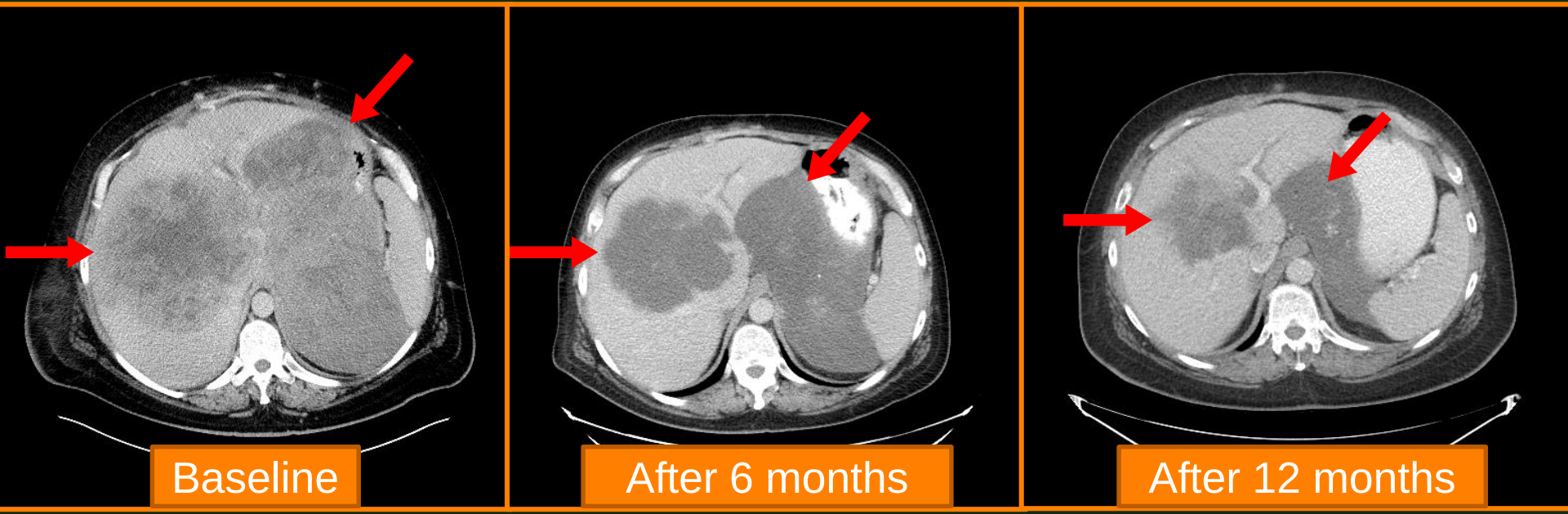
*Patients with confirmed response. DOR was defined as the time from first documented response (CR/PR) to the date of the first documented disease progression or death due to any cause, whichever came first. Patients without confirmed CR/PR were excluded from this analysis. 4L, 4th line; CI, confidence interval; CR, complete response; mDOR, median duration of response; NE, not evaluable; PR, partial response. A DOR was defined as the time from first documented response (CR/PR) to the date of first documented disease progression or death due to any cause, whichever came first. Patients without confirmed CR or PR were excluded from this analysis. Patients who were still in response at time of data cutoff were censored at their last valid assessment.

CONCLUSIONS

The NAVIGATOR trial demonstrated clinical activity and favorable tolerability in advanced Exon 18 mutant PDGFRA and 4L+ GIST.

- Avapritinib showed **remarkable activity in both D842V**, a previously undruggable target, and other Exon 18 mutant PDGFRA GIST
- Avapritinib displayed **response rates exceeding that reported** with other TKIs which were **durable.**
- The **safety profile of avapritinib is predictable and manageable**, thus allowing for prolonged treatment in patients benefiting from avapritinib
- Based on the safety profile and antitumor activity, avapritinib 300 mg QD is the recommended dose for patients with advanced GIST

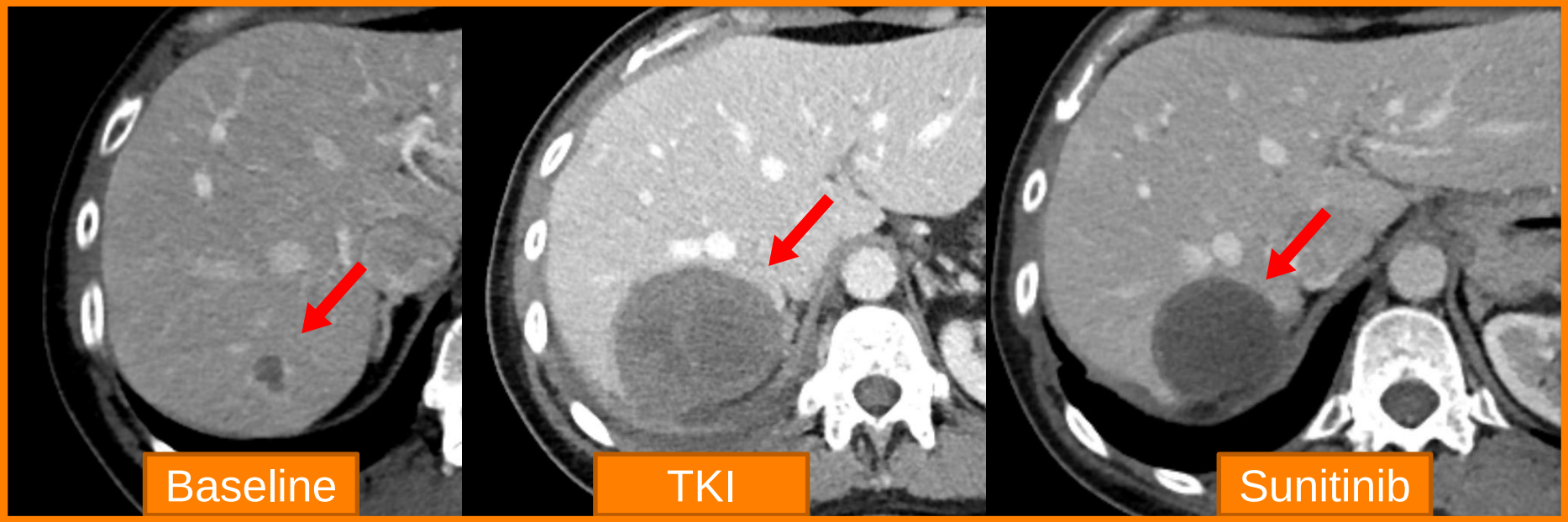
- 55 YO man with Gastric, ***KIT* exon 11 (W557-K558del)** mutant, GIST with liver metastases
- Progressive on imatinib, nilotinib, sunitinib, regorafenib.
- ctDNA revealed ***KIT* exon 17 Y823D** resistance mutation
- Placed on **Ponatinib** to target *KIT* exon 17



Arshad et al, ASCO 2018

Junaid Arshad, Jonathan C. Trent. JCO Precision Oncology 2020 :4, 66-73

- 52 YO woman with small intestine, ***KIT* exon 11 (L576P)** mutant, GIST with liver metastases
- Progressive on imatinib placed on **regorafenib** with rapid progression
- ctDNA revealed ***KIT* exon 13 V654A** resistance mutation
- Placed on **Sunitinib** to target *KIT* exon 13



Junaid Arshad, Jonathan C. Trent. JCO Precision Oncology 2020 :4, 66-73

Conclusion

- **Primary and resistance mutations should be determined in order to provide optimal therapy for GIST patients.**
- Liquid biopsy, ctDNA, is a rapid, non-invasive tool to detect mutations
- Avapritinib and ripretinib are new active agents for GIST patients.
- Earlier lines of therapy?
- Neoadjuvant or Adjuvant?
- Combinations?

Sylvester Comprehensive Cancer Center

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New Horizons 2021

New Agents for GIST Patients

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